



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ACA 6284 WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/12834	International filing date (day/month/year) 13.11.2003	Priority date (day/month/year) 15.11.2002
International Patent Classification (IPC) or both national classification and IPC C07C253/34		
Applicant AKZO NOBEL N.V et al		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand  07.06.2004	Date of completion of this report  06.12.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  O'Sullivan, P  Telephone No. +31 70 340-4511 	

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**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-20
	No: Claims	
Inventive step (IS)	Yes: Claims	1-20
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Re: Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: US 2002/120005 A1

D2: US-A-4 575 434

**1. Novelty (Art 33(2) PCT)**

1.1 D1 relates to a process for the preparation of of citalopram ([0001]) wherein an impurity, desmethyl citalopram, is separated from the citaopram in a purification process, the amide-like compound being removed by an acid/base wash or crystallisation ([0024]). D1 does not disclose solutions of amides and fatty acid-derived nitriles as is required by the process of independent claims 1 and 15.

The subject-matter of claims 1-20 is therefore considered novel over D1.

1.2 D2 discloses a process for the removal of long-chain aliphatic amides from a solution of said amides and fatty acid derived nitriles. In D2 both a layered mineral comprising an aluminium silicate and an acid strong enough to protonate said amides is employed. The process of D2 operates by the adherence of the protonated amides to the surface of said layered mineral and the precipitation of a salt of the acid. The precipitate and layer mineral are then removed by filtration. D2 differs from the present application in that in the former, no acid layer is formed and therefore, of course, an acid layer is not separated from said solution.

The subject-matter of claims 1-20 is therefore considered novel over D2.

**2. Inventive Step (Art 33(3) PCT)**

D2 is considered as the closest prior art since it is also concerned with a process for the removval of long-chain aliphatic amides from a solution of said amides and fatty acid derived nitriles. One of the differences between D2 and the present application is detailed in 1.2, above. Another difference, not included in the main claim of D2 but apparent from claim 3 and all of the examples therein is that the separation is carried out under partial vacuum. The effect of these differences, on comparing tables 1-8 of D2 with the example of the present application (page 8) appears to be a more efficient removal of amides in the present appclication. Comparing the example in the present

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application wherein 0.19% amide content is reduced to undetectable ( $<0.02\%$ ) with example III of D2 where 0.36 wt % amides was reduced only by 56-72% (see table 5), the present process is clearly more effective in removing amide impurities. Thus, the problem underlying the present application may be formulated as the provision of an improved process for the removal of long-chain aliphatic amides from a solution of said amides and fatty acid derived nitriles. The solution offered by present claims 1-20 represents both an improvement and a simplification of the process of D2 and is not considered obvious to the skilled person in light of the content of D2.

The subject-matter of claims 1-20 is therefore considered inventive.

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